

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

58777.000018

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)

10/560378

INTERNATIONAL APPLICATION NO.

PCT/JP2004/008205

INTERNATIONAL FILING DATE

June 11, 2004

PRIORITY DATE CLAIMED

June 13, 2003

TITLE OF INVENTION

PHARMACEUTICAL COMPOSITIONS FOR PREVENTING OR TREATING TH1-MEDIATED IMMUNE DISEASES

APPLICANT(S) FOR DO/EO/US

Topshiyuki HORI

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An Assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A Preliminary Amendment.
14. ☒ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A power of attorney and/or change of address letter.
16. ☒ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.
17. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
18. ☒ Other items or information:

Copy of WO 2004/110489; Verified English Language Translation of International Application PCT/JP2004/008205 (including Specification (pages 1-30); 25 Claims (pages 31-34); Abstract (page 35); Figures 1-5 (3 pages); Sequence Listing (4 pages)); Submission of Sequence Listing; Computer Readable Form (3 1/2 diskette) of the Sequence Listing; Notification Concerning Submission or Transmittal of Priority Document (PCT/IB/304); Second and Supplementary Notice Informing the Applicant of the Communication of the International Application (To Designated Offices Which Apply the 30 Month time Limit Under Article 22 (1)) (PCT/IB/308); Copy of International Search Report of PCT/JP2004/008205 (PCT/ISA/210); Information Disclosure Statement and PTO/SB/08A with 10 references.

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.7)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
10/560378		PCT/JP2004/008205		58777.000018	
The following fees have been submitted:				CALCULATIONS	PTO USE
19.	<input checked="" type="checkbox"/> Basic National Fee (37 CFR 1.492(a))	\$ 300.00	\$	300.00	
20.	<input checked="" type="checkbox"/> Examination Fee (37 CFR 1.492(c))		\$	200.00	
If the written opinion prepared by ISA/US or the International Preliminary Examination Report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)		\$ 0.00			
All other situations		\$ 200.00			
21.	<input checked="" type="checkbox"/> Search Fee (37 CFR 1.492(b))		\$	400.00	
If the written opinion of the ISA/US or the International Preliminary Examination Report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)		\$ 0.00			
Search Fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority		\$ 100.00			
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB		\$ 400.00			
All other situations		\$ 500.00			
TOTAL OF ABOVE CALCULATIONS =		\$ 900.00	\$	900.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing filed in an electronic medium) (37 CFR 1.492(j)). The fee is \$250.00 for each additional 50 sheets of paper or fraction					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100	/50		x \$250.00		
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h))			\$		
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	25 - 20 =	5	x	\$ 50.00	\$ 250.00
Independent claims	4 - 3 =	1	x	\$200.00	\$ 200.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+	\$360.00	\$
TOTAL OF ABOVE CALCULATIONS =			\$	450.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees above are reduced by 1/2.					\$
SUBTOTAL =			\$	1350.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).			+	\$	
TOTAL NATIONAL FEE =			\$		
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property			+	\$	
TOTAL FEES ENCLOSED =			\$	1350.00	

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.7) <div style="text-align: center; font-size: 1.5em; font-weight: bold;">10/560378</div> TBA	INTERNATIONAL APPLICATION NO. PCT/JP2004/008205	ATTORNEY'S DOCKET NUMBER 58777.000018
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a. ☒ A check in the amount of \$1350.00 to cover the above fees is enclosed.

b. ☐ Please charge Deposit Account No. 50-0206 in the amount of \$_____ to cover the above fees.

A duplicate copy of this sheet is enclosed.

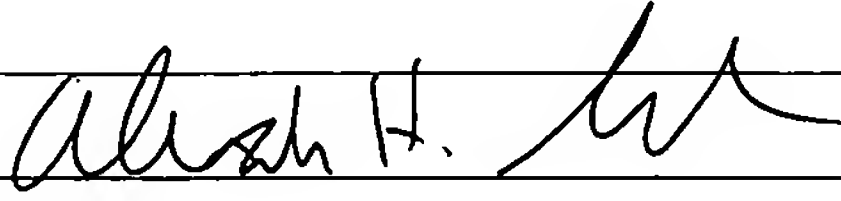
c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0206 A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

CUSTOMER NO. 21967
 Intellectual Property Department
 Hunton & Williams LLP
 1900 K Street, N.W.; Suite 1200
 Washington, DC 20006-1109
 (202) 955-1500 (telephone)
 (202) 778-2201 (facsimile)



SIGNATURE

Robert M. Schulman; Alexander H. Spiegler

NAME

31,196; 56,625	December 13, 2005
REGISTRATION NUMBER	DATE